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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/691,205 | 10/21/2003 | Arthur L. Holden | FGTI-P02-004 | 5634 |

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EXAMINER

OUELLETTE, JONATHAN P

ART UNIT PAPER NUMBER

3629

DATE MAILED: 12/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---------------------------------------|--|--|
| Office Action Summary | Application No. 10/691,205 | Applicant(s) HOLDEN, ARTHUR L. | |
| | Examiner Jonathan Ouellette | Art Unit 3629 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,9,13-15 and 21-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,9,13-15 and 21-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Claims 2-8, 10-12, and 16-20 have been cancelled, and Claims 21-42 have been added; therefore Claims 1, 9, 13-15, and 21-42 are currently pending in application 10/691,205.

Double Patenting

2. The rejection of Claims 1-20 under the judicially created doctrine of double patenting is withdrawn, due to Applicant's amendments.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. **Claims 1, 9, and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**
5. **Independent Claims 1, 9, and 15** describe a method/system for storing genetic information and authorizing access to said genetic information for the purpose of testing; however, it is unclear who performs the testing on the genetic information – third party, system administrator, or automated system.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. **Claim 15 is rejected under 35 U.S.C. 102(e) as being anticipated by Beecham (US 5,897,989).**
8. As per **independent Claim 15**, Beecham discloses a system comprising: a database; a medical testing system; and a processing system (Fig.1, 2, and 3).
9. As for the limitations of the functions of the system/apparatus or what the system/apparatus does, i.e. “storing genetic data of patients, performing tests on genetic data, and providing secured data access to authorized third parties”, these carry no patentable weight in an apparatus claim. Apparatus claims should cover what a device is or structures or structural elements, not what a device does. See Hewlett-Packard Co. vs. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990).
10. Furthermore, the system described by Beecham could be programmed to complete all the functions disclosed in Independent claim 15; as storing data (database manipulation), testing data (testing system manipulation), and controlling data access (processing system manipulation), were all well known forms of data handling/manipulation to one of ordinary skill in the art at the time the invention was made.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. **Claims 1, 9, 31, 34, 35, 38, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelkin et al. (Nelkin, Dorthy; Andres, Lori, "Homo Economics: Commercialization of Body Tissue in the Age of Biotechnology." The Hastings Center Report, 30(1), September 1998) in view of Rozen et al. (6,073,106).**

13. As per **independent Claim 1**, Nelkin discloses a method comprising, having a user provide a physical sample and having said physical sample processed to generate information representative of genetic data associated with the physical sample (creating a human gene databank, pg.4); providing the information in an accessible format; and allowing third-parties access the to information for testing purposes (Access provided to outside contractor, pg.4).

14. Nelkin fails to expressly disclose any data security protocols for the release of the information.

15. Rozen teaches the use of data security measures in order to protect saved information, by establishing access rights to the information; receiving a request from a third party user to access the information; comparing the third party user's request with the access rights to

confirm that the third party is authorized to access the information; and processing the request if appropriate (Abstract, Fig. 1A, C5 L1-11, C12 L13-23).

16. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the data security measures disclosed by Rozen in the genetic information storage system disclosed by Nelkin, for the advantage of providing a method of storing and testing genetic information, with the ability to increase security/privacy of the stored information, by implementing safety protocols on the release of the stored information.
17. As per **independent Claim 9**, Nelkin discloses a method comprising, receiving from a third party user a request to access stored genetic data of a patient to perform a genetic testing (Access provided to outside contractor, pg.4).
18. Nelkin fails to expressly disclose any data security protocols for the release of the information.
19. Rozen teaches the use of data security measures in order to protect saved information, by establishing access rights to the information; receiving a request from a third party user to access the information; comparing the third party user's request with the access rights to confirm that the third party is authorized to access the information; and processing the request if appropriate (Abstract, Fig. 1A, C5 L1-11, C12 L13-23).
20. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the data security measures disclosed by Rozen in the genetic information storage system disclosed by Nelkin, for the advantage of providing a method of storing and testing genetic information, with the ability to increase

security/privacy of the stored information, by implementing safety protocols on the release of the stored information.

21. Nelkin also fails to expressly disclose wherein the genetic testing includes a test to determine the presence or absence of a gene or genetic variant or level of expression of a marker associated with a specified disease.
22. However these differences are only found in the nonfunctional descriptive data and are not functionally involved in the steps recited. The genetic storage and testing method would be performed regardless of the type of medical test used/completed. Thus, this descriptive data will not distinguish the claimed invention from the prior art in terms of patentability, *see In re Gulack*, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983); *In re Lowry*, 32 F.3d 1579, 32 USPQ2d 1031 (Fed. Cir. 1994).
23. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to complete a multitude of tests/test types on the stored genetic information, because such data does not functionally relate to the steps in the method claimed and because the subjective interpretation of the data does not patentably distinguish the claimed invention.
24. Finally, Nelkin fails to expressly disclose the use of the Internet for sending the request for information.
25. However, It was known at the time of the invention that merely providing an automatic means to replace a manual activity which accomplishes the same result is not sufficient to distinguish over the prior art, *In re Venner*, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958). For example, simply automating the step of requesting genetic information, gives just

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what one would expect from the manual step as shown in *Nelkin*. In other words, there is no enhancement found in the claimed step other than the known advantage of increased speed.

The end result is the same as compared to the manual method.

26. Therefore, It would have been obvious to a person of ordinary skill in the art at the time of the invention to automate the step of requesting genetic information, because this would speed up the determining step which is purely known and expected result from automation of what is known in the art.

27. As per Claim 31, *Nelkin* and *Rozen* disclose allowing the user to provide information about a patient associated with the physical sample for storing the patient information with data generated from the physical sample.

28. As per Claim 34, *Nelkin* and *Rozen* disclose providing an indication to a user when a request to access data associated with the user has been denied.

29. As per Claim 35, *Nelkin* and *Rozen* disclose allowing the user to grant access rights to the denied request.

30. As per Claim 38, *Nelkin* and *Rozen* disclose storing test results in a database.

31. As per Claim 42, *Nelkin* and *Rozen* disclose wherein the conditions include conditions representative of third parties allowed access and users for which access is allowed (establishing access rights).

32. **Claims 13, 14, 21-30, 32, 33, 36, 37, and 39-42 are rejected under 35 U.S.C. 103 as being unpatentable over *Nelkin* in view of *Rozen*.**

33. As per Claim 13, 14, 21-30, 32, 33, 36, 37, and 39-42, Nelkin and Rozen fail to expressly disclose the multitude of genetic testing types, types of genetic information generated, physical sample types, types of users or third parties described in the instant application.
34. However these differences are only found in the nonfunctional descriptive data and are not functionally involved in the steps recited. The genetic storage and testing method would be performed regardless of the type of medical test used/completed, information generated, physical sample types, types of users or third parties used/participating in the method. Thus, this descriptive data will not distinguish the claimed invention from the prior art in terms of patentability, *see In re Gulack*, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983); *In re Lowry*, 32 F.3d 1579, 32 USPQ2d 1031 (Fed. Cir. 1994).
35. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made used a multitude of genetic testing types, types of genetic information generated, physical sample types, types of users or third parties, because such data does not functionally relate to the steps in the method claimed and because the subjective interpretation of the data does not patentably distinguish the claimed invention.

Response to Arguments

36. Applicant's arguments filed 10/11/2005 have been fully considered but are moot in view of the new ground(s) of rejection.
37. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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38. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

39. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan Ouellette whose telephone number is (703) 605-0662 ((571) 272-6807 effective April 13, 2005). The examiner can normally be reached on Monday through Thursday, 8am - 5:00pm.
40. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Weiss can be reached on (703) 308-2702. The fax phone numbers for the organization where this application or proceeding is assigned (703) 872-9306 for all official communications.
41. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 306-5484.

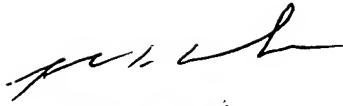
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December 21, 2005



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